



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kasibhatla *et al.*

Appl. No. 09/920,332

Filed: August 2, 2001

For: **Methods of Identifying  
Immunosuppressive Agents**

Confirmation No. 5774

Art Unit: 1644

Examiner: Saunders, D.

Atty. Docket: 1735.0470001/RWE/ALS

**Reply To Restriction Requirement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated May 5, 2003, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group I, represented by claims 1-13 and 28-31. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. This election is made **with** traverse.

***Traversal of the Restriction Requirement***

The criteria for a proper requirement for restriction are that (1) the inventions must be independent or distinct as claimed; *and* (2) there must be a serious burden on the Examiner if restriction is not required. MPEP § 803 (emphasis added). The two requirements for restriction set forth in MPEP § 803 are connected with "and." Accordingly, satisfaction of both criteria is required. Moreover, the "serious burden" must be shown by demonstrating at least one of the following: a) separate classification of the subject matter;

RECEIVED  
JUN 04 2003  
TECH CENTER 1600/2900

b) that the subject matter has attained separate status in the art when they are classifiable together; or c) different fields of search for the subject matter. *See* MPEP § 808.02.

Applicants respectfully assert that the Examiner has not fully satisfied the second criteria of MPEP § 803. Groups I-IV are closely related in subject matter. As such, a search of one group of claims is likely to encompass subject matter pertinent to the patentability of all groups. Moreover, groups I and II have been classified by the Examiner in class 435, subclass 7.24; and groups III and IV have both been classified by the Examiner in class 514, subclass 1+ and in class 424, subclass 278.1+.

To the extent that the claims of each of these groups are classified in the same class and subclass, the Examiner has not demonstrated any burden in examining the claims together. Moreover, the Examiner has provided no indication as to how the subject matter of the claims has attained separate status in the art when they are classifiable together, or that different fields of search would be necessary. Finally, the identical classification of the claims in their respective groups suggests that different fields of search would not be necessary for the identically classified groups.

The Examiner has alleged that inventions I and II are unrelated. *See* PTO File Wrapper Paper No. 8, p. 2, line 11. In particular, the Examiner states that "the different inventions have different modes of operation, since the affecting of cell viability, as recited

in the method of Group II, has *nothing* to do with the caspase pathway." *Id.* at lines 13-15, emphasis added. Applicants respectfully disagree and direct the Examiner's attention to paragraphs 10-14 of the written description. These paragraphs discuss the relationship between cell viability and the caspase pathway.

between cell viability and the caspase pathway.

This is  
will  
different  
search  
terms required  
for US patent  
for literature  
search.

or what  
measurement  
of caspase  
activity  
in group I  
is not a  
measurement  
of cell viability  
as in Group II

This claim  
14 is not  
generic to  
caspase

caspase  
activity is  
merely a  
precursor  
to cell  
death

The Examiner has also alleged that inventions I and IV are distinct despite the proviso of claim 34 because "the agent *could* have been identified by other methods." *Id.* at lines 20-21, emphasis added. Applicants respectfully point out that whether the agent *could* have been identified by another method is irrelevant. Claims 34 and 35 *require* that the agent be identified according to the method of claim 1. The Examiner also states that "the proviso would not impart patentability to any known composition (e.g. a tree bark or root extract) which has merely been further characterized as to its inherent properties by the assay of claim 1." *Id.* at p. 2, line 21 to p. 3, line 2. Applicants respectfully point out that this allegation is also irrelevant insofar as it does not independently support distinctness under MPEP § 806.05(f) or satisfy the requirements for a restriction requirement under MPEP § 803 (shown above).

Applicants also respectfully point out that it has not been demonstrated how Inventions I and III, II and III, or II and IV are distinct from one another.

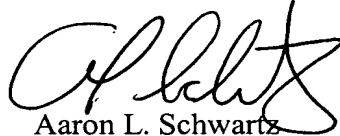
Hence, the Examiner has not shown by appropriate explanation any of the three reasons supporting a serious burden if restriction were not required. Moreover, the MPEP states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP § 803. Applicants respectfully assert that to the extent that claims of different groups are identically classified, the Examiner must examine these claims on the merits even though they may be directed to distinct or independent inventions. Moreover, all the groups should be examined together as the Examiner has not set forth a *prima facie* showing of their distinctness. Reconsideration and withdrawal of the Restriction Requirement is respectfully requested.

show  
argument  
process must  
be examined  
for the patent  
per se

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Aaron L. Schwartz  
Agent for Applicants  
Registration No. 48,181

Date: June 2, 2003

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600